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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,876	04/10/2001	Steven L. Stice	P 0280088	1054

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	2

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/828,876	Applicant(s) STICE ET AL.	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, 69-75 and 77, drawn to a method of cloning a mammal; a fetus; an offspring, a transgenic fetus; and organs, classified in class 800, subclass 24.

II. Claims 28-34, drawn to methods of producing a CICM cell line, a CICM cell line and differentiated cells, nontransgenic and transgenic, classified in class 435, subclass 395.

III. Claims 35-41 and 43-54 drawn to a method of treating Parkinson's Disease comprising administering a cell or a cell or a xenogenic cell, non-transgenic or transgenic cell, non-transgenic or transgenic, classified in class 424, subclass 93.2.

IV. Claims 35-40 and 43-54, drawn to a method of treating Huntington's Disease comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

V. Claims 35-40 and 43-54, drawn to a method of treating Alzheimer's Disease comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

VI. Claims 35-40 and 43-54, drawn to a method of treating ALS comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

VII. Claims 35-40 and 43-54, drawn to a method of treating spinal cord defects or injury comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

VIII. Claims 35-40 and 43-54, drawn to a method of treating multiple sclerosis comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

IX. Claims 35-40 and 43-54, drawn to a method of treating muscular dystrophy comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

X. Claims 35-40 and 43-54, drawn to a method of treating cystic fibrosis comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XI. Claims 35-40 and 43-54, drawn to a method of treating liver disease comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XII. Claims 35-40 and 43-54, drawn to a method of treating diabetes comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XIII. Claims 35-40 and 43-54, drawn to a method of treating heart disease comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XIV. Claims 35-40 and 43-54, drawn to a method of treating cartilage disease or defect comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XV. Claims 35-40 and 43-54, drawn to a method of treating burns comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XVI. Claims 35-40 and 43-54, drawn to a method of treating foot ulcers comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XVII. Claims 35-40 and 43-54, drawn to a method of treating vascular disease comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XVIII. Claims 35-40 and 43-54, drawn to a method of treating urinary tract diseases comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XIX. Claims 35-40 and 43-54, drawn to a method of treating AIDS comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XX. Claims 35-40 and 42-54, drawn to a method of treating cancer comprising administering a cell or a xenogenic cell, non-transgenic or transgenic cell, classified in class 424, subclass 93.2.

XXI. Claims 55-68 and 76, drawn to a method of producing a chimeric nonhuman embryo, fetus or mammal using an NT unit, chimeric embryo, chimeric fetus, and chimeric offspring, all nontransgenic or transgenic, classified in class 800, subclass 24.

The inventions are distinct, each from the other because:

Inventions I and II are drawn to distinct methods. Inventions I is for the production of a cloned nonhuman mammal. Inventions II is for the production of a CICM cell line.

Inventions I and any one of III-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the clone nonhuman mammals of invention I can be used to establish herds of cloned nonhuman mammals.

Inventions I and XXI are mutually exclusive and independent methods. Inventions I requires the insertion of a differentiated mammalian cell as nuclear donor. Invention XXI requires a NT unit to be inserted into a blastocyst. These methods require materially different and separate protocols. Further, neither method is required for the other method.

Inventions II and any one of III-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cloned CICM cells of invention II can be used to produce cloned nonhuman mammals.

Inventions II and XXI are mutually exclusive and independent methods. Inventions II requires the insertion of a differentiated mammalian cell into an enucleated oocyte as nuclear donor. Invention XXI requires a NT unit to be inserted into a blastocyst. These methods require materially different and separate protocols. Further, neither method is required for the other method.

Inventions III-XX are mutually exclusive methods of treating various diseases. Each of the claimed diseases comprises separate and materially different symptoms, and would require materially different and separate protocols for treatment. Further, the treatment of any one of these diseases is not needed for the implementation of the treatment for any other of the diseases.

Inventions III-XX and XXI are to mutually exclusive and independent methods. Inventions III-XX are drawn to methods of treating various diseases by cell therapy. Invention XXI is to a method of producing a chimeric nonhuman mammal. None of inventions III-XIX are required for the implementation of invention XX, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown in some cases by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of Claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Ms. Pauline Farrier, whose telephone number is (703) 305-3550.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Dr. D. Crouch
September 27, 2002